Rapid Infectious Diseases Diagnostic Test Transferable Research and Development (R&D) Tax Credit

Proposed by the Infectious Diseases Society of America

The Infectious Diseases Society of America (IDSA) is an organization of more than 10,000 infectious diseases (ID) physicians, scientists, and other health care professionals dedicated to promoting health through excellence in ID research, education, patient care, prevention, and public health. The Society was founded in 1963 and is based in Arlington, Va. For more information on IDSA, see www.idsociety.org. For more information, contact Amanda Jezek, IDSA's Director of Government Relations at 703-740-4790 or ajezek@idsociety.org.

Background: Why Rapid Infectious Diseases Diagnostic Tests are Needed

- New rapid, highly accurate infectious diseases diagnostic tests are sorely needed to improve patient care by allowing for earlier and more appropriate treatment. Rapid diagnostics can mean the difference between life and death for patients with serious, aggressive infections. For example, current diagnostic tests for sepsis (acute organ dysfunction secondary to infection) typically require 1-5 days to complete. Early appropriate sepsis therapy improves outcomes, but 20-30% of patients with severe sepsis receive inadequate delayed therapy.

- Many different diseases can present with similar symptoms, making diagnostic tests a critical tool when determining, for example, whether to treat a patient for bacterial pneumonia, viral pneumonia, or complications of asthma or chronic obstructive pulmonary disease (COPD). Treatment differences may include not only which drugs to prescribe, but also whether a hospital stay is needed. Beyond pathogen detection, diagnostics are used to determine disease activityand progression, and monitor effectiveness of therapy.

- Improved diagnostic tests will reduce the need for physicians to treat infections empirically, whichwill reduce inappropriate use of antibiotics—a key driver of the escalating antibiotic resistance crisis. Several studies have found that 50% or more of outpatients presenting with acute upper respiratory tract infections receive antibiotics even though the majority of these illnesses are caused by viruses. In these cases, antibiotic prescribing is often due to an inability to rule out bacterial infection and physician's cautious concern about withholding treatment for a possible bacterial infection.

- Some current diagnostic tests are insufficient for optimal patient care. For example, in some cases rapid influenza tests cannot rule out influenza infection, thus clinicians must often use clinical judgment alone to determine antiviral treatment, resulting in both over and under-treatment of patients with influenza. In addition, diagnostic tests for invasive fungal infections do not provide sufficient, timely information to physicians, causing delayed initiation of appropriate antifungal therapy, which is linked to poor outcomes.

- Unmet diagnostic needs also impact epidemiology and infection prevention. Swift identification of antibiotic resistance is central to timely isolation of patients infected with drug-resistant organisms. Prompt outbreak detection is central to preventing and limiting the spread of disease.

- Antibiotic and antifungal R&D is lagging, and we are in desperate need of new drugs. There are serious challenges to enrolling eligible patients in clinical trials for these antimicrobials. Rapid diagnostics are a fundamental part of the solution, as they will reduce the trial costs by more rapidly identifying eligible patients for the clinical trial.

Background: Economic Barriers to Infectious Diseases Diagnostic Tests R&D

- Unfortunately, there is little impetus for companies to develop rapid diagnostic tests, and the high cost of R&D for these products poses significant barriers.

- While the federal tax code provides a credit for research and experimentation (commonly known as the R&E or R&D tax credit), the incentive has not proven sufficient to incentivize R&D for rapid infectious diseases diagnostic tests.

- Many laboratories available for diagnostics research lack the particular expertise needed to evaluate the new product (e.g., viral culture, or extraction of RNA from clinical samples), requiring companies to provide costly training and supervision. Locating or developing a sufficient number of laboratories with the appropriate expertise to process the large number of samples needed for a clinical trial is becoming too costly for many companies to pursue.

- Participating laboratories may need to run multiple tests to establish a "patient infected status" in order to validate a new diagnostic. This strategy has been applied successfully in multiple product evaluations but is very expensive, dramatically increasing the cost of clinical trials. The cost of one effective validation method, nucleic acid sequence analysis, can add over $100,000 to the cost of a clinical trial. That may be prohibitive, particularly for smaller companies.

- Accessing test materials for rare pathogens also can be difficult and costly, as many clinical laboratories do not preserve specimens containing novel or unusual organisms for further work up. Even when such crucial samples are available, the cost of accessing them has become prohibitive, in many cases.

IDSA's Proposed Transferable R&D Tax Credit

- Given the challenges described above, IDSA is launching an effort to enact a new federal tax incentive for research on rapid (less than four (4) hours) diagnostic tests that detect and identify serious or life-threatening infectious diseases. The key elements of the new tax incentive are as follows:

    - ✓ Establish new provision in the Internal Revenue Code §45 -- Clinical Testing Expenses for Infectious Diseases Diagnostic Tests.
    - ✓ Provide a credit of 50% of the qualified clinical testing expenses for the taxable year.
    - ✓ Use the basic structure of the Orphan Drug Tax Credit (IRC §45C) the R&D tax credit (IRC §41), and:
        - Replace §41 language "qualified research" with "clinical testing," and
        - Increase to 100% from 65/75% the level of contract research expenses that would be treated as clinical testing expenses.
    - ✓ Clinical testing conducted outside the U.S. would not be an eligible expense, unless there is an insufficient U.S. testing population and the testing is conducted by a U.S. person or by another person not related to the taxpayer.

- ✓ Clinical testing expenses would not include amounts funded by a grant, contract or by another person or governmental entity.
- ✓ Clinical testing expenses must relate to a qualified diagnostic test that has received a prior designation from the U.S. Food and Drug Administration (FDA). A legislative framework must be established that provides FDA the authority and mandate to designate eligible products prior to when clinical testing commences.
- ✓ The provisions of the credit would be applied separately to each designated "qualified diagnostic test" tested by the taxpayer.
- ✓ The term 'qualified diagnostic test' means an in-vitro diagnostic (IVD) device used to identify or detect the presence, concentration, or characteristics of an infectious disease and/or pathogen.
- ✓ The credit would apply to IVDs relating to testing for all infectious diseases (namely bacterial and fungal infections, as well as viral, pathogen, and sera or gamma globulin related).
- ✓ The credit would apply only to those infectious disease IVDs that are related to serious or life threatening conditions, namely those that would be approved as Class II or Class III medical devices through the FDA.
- ✓ Only rapid diagnostic tests, i.e. only IVDs that provide results in less than four hours, would be eligible for the credit.
- ✓ In addition only clinical testing of the related diagnostics would be eligible for the credit, not internal analytical testing performed prior to human testing.
- ✓ Unused credits would be transferable for use by a qualified diagnostics research taxpayer, which is defined as any domestic corporation the primary mission of which is diagnostics research and/or development. This will enable emerging (small) companies without tax liability to sell the credit to established, profitable companies so that the emerging company may then invest this sales income into additional drug R&D.
- ✓ Qualified clinical testing shall be taken into account in determining base period research expenses for applying the R&E tax credit (IRC §41) to subsequent taxable years.
- ✓ The Infectious Diseases Diagnostic Test Transferable R&D Tax Credit would be permanent.

- IDSA is currently working with Ernst and Young to develop a cost estimate for this proposal, which we hope to share with the Committee in early summer 2013.

- IDSA looks forward to an opportunity to work with the Committee to refine and target this proposed tax credit to the most serious and life threatening infections for which new rapid diagnostic tests are most needed.